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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,636	06/28/2001	Malcolm King	032942-032	5976
7590	06/27/2002			
Gerald F. Swiss BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			EXAMINER KHARE, DEVESH	
			ART UNIT 1623	PAPER NUMBER 6
			DATE MAILED: 06/27/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/892,636	KING ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 13-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 13-37 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**35 U.S.C. 112, second paragraph rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claims 13, 24 and 29 are rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13, 24 and 29 are unclear with regard to the phrase “polysaccharide having about the same number of hydrogen bonding sites as dextran”.

**35 U.S.C. 112, first paragraph rejection**

Claims 15, 27 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 15, 27 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improving mucus clearance by administering dextran to the respiratory tract at a concentration of 4 to 40 mg/mL, does not reasonably provide enablement for all polysaccharides or other concentrations. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

As such one of ordinary skill in the art would have to undergo undue experimentation in order to practice the full scope of the applicants' invention.

The direction and guidance provided in the specification is directed towards administering dextran at a concentration of 4 to 40 mg/mL. Although polysaccharides (oligomers of galactose and fucose and the amino sugars glucosamine and galactosamine) are mentioned in the specification (page 8, lines 11-17), no specific polysaccharides are mentioned nor are they used in any working examples. The applicants' state that the nature of the invention (i.e. to increase mucus clearance by dextran administration) was "dose dependent" (see page 6, lines 12-14 under the heading "Detailed Description of the Invention"). Further, the means by which other polysaccharides may show the same type of activity as dextran, ( i.e. the number of hydroxy moieties available or stereochemical complement to oligosaccharide moieties natives to respiratory tract mucins), is hinted at but not conclusive. The structure of dextran (a polysaccharide with a poly  $\alpha$ -D-(1 $\rightarrow$ 6)-Glc with periodic (1 $\rightarrow$ 3) branch points to  $\alpha$ -D-Glc oligosaccharides) differs greatly in structure from other unsubstituted polysaccharides such as cellulose, starch,  $\beta$ -glucans, etc. in addition to other polysaccharides with hydroxy moieties substituted with other moieties or which forms deoxy sugars (e.g. glycosaminoglycans). Even in relation to other (1 $\rightarrow$ 6) linked polysaccharides, the conformational aspects of dextran which provided the desired activity cannot be assumed for other like polysaccharides. The breadth of the claims is

intended to be inclusive for all polysaccharides and the time and expense necessary to determine enabling polysaccharides would be prohibitive without further guidance, examples or a conclusive explanation for the mechanism by which dextran exerts its effects. It is well known and established that the "law requires that disclosure in an application shall inform those skilled in the art how to use appellant's alleged discovery, not how to find out how to use it for themselves." *In re Gardner et al.*, 166 USPQ 138(CCPA 1970).

**Provisional "Non-Statutory" Double Patenting Rejection**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,339,075. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are broadly directed toward a method of improving mucus clearance by administering a polysaccharide having about the same number of hydrogen bonding sites as dextran at a concentration of 4 to 40 mg/mL to a

patient in need of such treatment. Further limitations include the inclusion of a carrier and the type of lung disease being treated where mucus build up occurs which encompass the invention cited in claims 1-23 of U.S. Patent No. 6,339,075 which are directed toward the use of dextran and other polysaccharides to improve mucus clearance.

The claims in U.S. Patent No. 6,339,075 differ from the present application in that it does not include the polysaccharide comprises oligomers of galactose and fucose and the amino sugars glucosamine and galactosamine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### **State of the Art References**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Speert et al. (U.S. Patent #5,514,665)- discloses a method of reducing the risk of infection by bacterial pathogens (*Pseudomonas aeruginosa* is the pathogen cited in the specification) by administering an effective amount of dextran with a pharmaceutically acceptable diluent or carrier.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devesh Khare whose telephone number is (703)605-1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (703)308-4532. The official fax phone numbers for the organization where this application or proceeding is assigned is (703)308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

  
Devesh Khare, Ph.D.,JD(2Y).  
Art Unit 1623  
June 25,2002

  
SAMUEL BARTS  
PRIMARY EXAMINER  
GROUP 1600